K131363

510(k) Summary
(as required by section 807.92(c).

Sponsor	LifeScan Europe, a Div. of Cilag GmbH International Gubelstrasse 34 Zug, Switzerland 6300
Correspondent	Oyinkan Donaldson, Regulatory Affairs Manager LifeScan Scotland Ltd Beechwood Business Park North Inverness, Scotland IV2 3ED United Kingdom Phone: +44(0) 1463 721259 Mobile: 44 (0) 7909 935151 Fax: 44 01463 722000 Email: odonalds@its.jnj.com
510(k) Author	Fiona Leeper, Senior Regulatory Affairs Specialist LifeScan Scotland Ltd. Beechwood Park North Inverness, IV2 3ED, UK
Date Prepared	9th May 2013
Device Trade Name	OneTouch Verio Blood Glucose Monitoring System
Common Name	Glucose Test System
Classification	OneTouch Verio Blood Glucose Meters and OneTouch Verio Test Strips are Class II devices (21 CFR § 862.1345), Product Code NBW, LFR

AUG 30 2013

System Description	The OneTouch® Verio® Blood Glucose Monitoring System consists of the OneTouch® Verio® Sync Blood Glucose Meter, OneTouch® Verio® Test Strips, OneTouch® Verio® Level 3 and Level 4 Control Solutions, Lancing Device and Sterile Lancets. The OneTouch® Verio® Blood Glucose Monitoring System measures the glucose content of a blood sample by means of an electrical current produced in the test strip and sent to the meter for measurement.
Predicate Device	OneTouch® Verio®IQ Blood Glucose Monitoring System (K110637, cleared on Sept 07, 2011)
Intended Use/Indications for Use	The OneTouch Verio® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips. The system is intended to be used by a single patient and should not be shared. The OneTouch Verio® Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The OneTouch Verio® Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes or for neonatal use. The OneTouch® Verio® Test Strips are for use with the OneTouch® Verio® Blood Glucose Meter to quantitatively measure glucose drawn from the fingertips.
Comparison to Predicate Device	The Subject device is different from the predicate device for the following aspects:

	• **Meter**: ergonomic/physical design, user interface, hardware, electronic and software changes. There are no changes to the OneTouch® Verio® Test Strips or the OneTouch® Verio® Level 3 and Level 4 Control Solutions as a result of this 510(k) submission. There have been no changes to the intended use, operating principle or scientific technology.
Technological Characteristics	There has been no change to the fundamental scientific technology, which is amperometric detection. The operating principle remains electrochemical reaction.
Summary of Performance Characteristics	The OneTouch® Verio® Blood Glucose Monitoring System (meter, strips, and control solutions) was tested in accordance with ISO 15197:2003(E). Analytical performance testing included system accuracy, repeatability, intermediate precision and linearity testing. A user performance evaluation assessed accuracy of results and usability of the device in the hands of intended users. The OneTouch® Verio® Blood Glucose Monitoring System performed similarly to both the predicate device as well as to a laboratory reference method, the Yellow Springs Instrument (YSI).

System Accuracy

A comparison of system accuracy performance demonstrated that the OneTouch® Verio® Blood Glucose Monitoring System and the OneTouch® Verio®IQ Blood Glucose Monitoring System are substantially equivalent.

System Accuracy Results for Glucose Concentrations <75 mg/dL (1st Replicate)
Number (and percent) of meter results that match the laboratory test

Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
50.7% (35/69)	89.9% (62/69)	100% (69/69)

System Accuracy Results for Glucose Concentrations ≥75 mg/dL (1st Replicate)
Number (and percent) of meter results that match the laboratory test

Within ±5%	Within ±10%	Within ±15%	Within ±20%
62.3% (144/231)	89.2% (206/231)	97.8% (226/231)	100% (231/231)

Precision
Within Run Precision (300 Venous Blood Tests per glucose level)

Target Glucose (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
40	51.50	1.26	2.44
100	108.59	1.91	1.76
130	145.72	2.91	2.00
200	206.92	4.30	2.08
350	382.27	7.69	2.01

Results show that the greatest variability observed between test strips when tested with blood is 2.44% or less.

Total Precision
(600 Control Solution Tests at each control solution level)

Glucose Level Ranges (mg/dL)	Mean Glucose (mg/dL)	Standard Deviation (mg/dL)	Coefficient of Variation (%)
Level 2 (38-62)	39.45	0.82	2.08
Level 3 (102-138)	117.81	2.22	1.88
Level 4 (298-403)	342.56	6.55	1.91

User Performance Evaluation
Subject Fingertip Results for Glucose Concentrations <75 mg/dL

Tester	Within ±5 mg/dL	Within ±10 mg/dL	Within ±15 mg/dL
Subject	7 of 20 (35%)	18 of 20 (90%)	19 of 20 (95%)

Subject Fingertip Results for Glucose Concentrations ≥75 mg/dL

Tester	Within ±5%	Within ±10%	Within ±15%	Within ±20%
Subject	95 of 169 (56.2%)	144 of 169 (85.2%)	161 of 169 (95.3%)	167 of 169 (98.8%)

Design verification and validation testing confirmed that the performance, safety, and effectiveness of the OneTouch® Verio® Blood Glucose Monitoring System was equivalent to that of the predicate device. The OneTouch® Verio® Meter met recognized electrical and safety standards.

Conclusions

The OneTouch® Verio® Blood Glucose Monitoring System is substantially equivalent in its intended use, performance, safety, effectiveness and the underlying scientific and operating principles used, to the predicate OneTouch® Verio®IQ Blood Glucose Monitoring System (K110637).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

Cilag GmbH International
C/O Oyinkan Donaldson
Regulatory Affairs Manager
LifeScan Europe
Gubelstrasse 34
ZUG, SWITZERLAND 6300

Re: k131363
Trade/Device Name: OneTouch Verio Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, LFR
Dated: July 25, 2013
Received: July 29, 2013

Dear Ms. Donaldson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k131363

Device Name: OneTouch® Verio® Blood Glucose Monitoring System

Indications for Use:

The OneTouch® Verio® Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertip. The system is intended to be used by a single patient and should not be shared.

The OneTouch® Verio® Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control.

The OneTouch® Verio® Blood Glucose Monitoring System is not to be used for the diagnosis of or screening of diabetes or for neonatal use.

The OneTouch® Verio® Test Strips are for use with the OneTouch® Verio® Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole drawn from the fingertips.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use X (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Devices and Radiologic Health (OIR)

Katherine Serrano -S

Division Sign-Off
Office of In Vitro Devices and Radiologic Health